

Remarks

In the outstanding Official Action, the Examiner:

(1) rejected claims 1-10 and 12-16 under 35 USC 103(a) as being unpatentable over Campbell in view of Hata et al.;

(2) rejected claims 11 and 28 under 35 USC 103(a) as being unpatentable over Campbell in view of Hata et al. as applied to claims 1 and 4-8 above, and further in view of Loch et al.; and

(3) rejected claim 17 under 35 USC 103(a) as being unpatentable over Campbell in view of Hata et al. as applied to claims 1, 4, 14-16 above, and further in view of Sherman et al.

In response to Item 1 above, Applicants respectfully traverse the rejection of claims 1-10 and 12-16 under 35 USC 103(a) as being unpatentable over Campbell in view of Hata et al. Reconsideration of claims 1-10 and 12-16 is respectfully requested.

Claim 1 of the present invention comprises an annuloplasty band comprising a ring of graft tissue. Referring to specification of the above-identified patent application at page 3, lines 4-11, an annuloplasty band or ring is a device configured to surround all or part of the circumference of the annulus of a valve. Furthermore, an annuloplasty band or ring as used in an annuloplasty procedure may function to remodel the annulus of the valve, decrease tension on suture lines, increase leaflet coaptation, prevent annular dilation, and improve repair durability.

Applicants believe that Campbell discloses an annuloplasty ring having separable ring portions, and an interconnecting member connecting the ring portions to one another. Campbell discloses that the ring portions are constructed of an inner silicone tube member within an outer polyester member. (Col. 4, lines 26-28.) Applicants believe that Campbell teaches away from the annuloplasty band of the present invention as claimed in claim 1 inasmuch as Campbell includes at least a section of the annuloplasty ring in which a braided suture is surrounded by both (1) a polymer tube (i.e., silicone tube member) with (2) a cloth covering (i.e., outer polyester member.) The flexible polymer tube provides shape to the annuloplasty ring and provides material for attachment of anchoring sutures. The outer polyester tube member provides a cloth cover to encourage cell ingrowth. (Col. 4, lines 26-32 and Col. 5, lines 1-20.) Applicants believe that Campbell does not disclose an annuloplasty band comprising a ring of graft tissue, such that the graft tissue provides shape to the annuloplasty ring, material for attachment of anchoring sutures, and encourages cell growth.

Applicants believe that Hata et al. disclose a natural tissue prosthetic valve assembly. Applicants have carefully reviewed Hata et al. and believe that Hata et al. indicates that the natural tissue prosthetic valve assembly "may be used in valvular prosthetics with or without...annuloplasty rings, or other

support frames. Further, [Hata et al.] may be used in connection with heterologous, homologous or autologous natural tissue valve leaflets including those derived from xenogenic valve assemblies, pericardial tissue or connective tissue and membranes such as fascia lata and dura matter." (Col. 4, lines 19-33, underlining added.) Applicants believe that Hata et al. disclose that the valve assembly may be used in valvular prosthetics with an annuloplasty ring, and the valve leaflets of the valve assembly may include natural tissue. Applicants believe that Hata et al. are silent with respect to the construction of annuloplasty rings used in valvular prosthetics together with a natural tissue prosthetic valve assembly. Accordingly, independent claim 1 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

Claims 2-10 and 12-16, which depend either directly or ultimately from independent claim 1, are believed to be in condition for allowance for at least the above-identified reasons. Accordingly, allowance of claims 2-10 and 12-16 is respectfully requested.

In response to Item 2 above, Applicants respectfully traverse the rejection of claims 11 and 28 under 35 USC 103(a) as being unpatentable over Campbell in view of Hata et al. as applied to claims 1 and 4-8 above, and further in view of Loch et al. Reconsideration of claims 11 and 28 is respectfully requested.

Loch et al. is not believed to constitute prior art with respect to the above-identified patent application inasmuch as the above-identified patent application claims benefit of U.S. Provisional Patent Application Serial No. 60/176,046, filed 01/14/2000. This filing date is prior to 11/29/2000, the effective date of the 1999 Amendment relating to 35 USC 102(e), and prior to 01/16/2001, the issue date of U.S. Patent No. 6,174,332. Inasmuch as Loch et al. is not believed to constitute prior art with respect to the above-identified patent application, and claims 11 and 28 each depend ultimately from independent claim 1, claims 11 and 28 are believed to be in condition for allowance for at least the above-identified reasons. Accordingly, allowance of claims 11 and 28 is respectfully requested.

In response to Item 4 above, Applicants respectfully traverse the rejection of claim 17 under 35 USC 103(a) as being unpatentable over Campbell in view of Hatz et al. as applied to claims 1, 4 and 14-16 above, and further in view of Sherman et al. Reconsideration of claim 17 is respectfully requested.

Applicants have carefully reviewed Sherman et al. and believe that Sherman et al. disclose an automatic purse string suture device to enable a surgeon to install a purse string suture in tissue structures. Applicants believe that Sherman et al. do not disclose an annuloplasty band comprising a ring of graft tissue.

Claim 17, which depends ultimately from claim 1, is believed to be in condition for allowance for at least the above-identified reasons. Accordingly, allowance of claim 17 is respectfully requested.

New claim 29 comprises an annuloplasty band comprising a sheet of graft tissue rolled upon itself and tightly packed to form a generally cylindrical shape. Inasmuch as Applicants believe that the prior art of record does not disclose an annuloplasty band comprising a sheet of graft tissue rolled into a generally cylindrical shape, new claim 29 is believed to be in condition for allowance. Accordingly, allowance of new claim 29 is respectfully requested.

In the event that any additional fees may be required to be paid in connection with this submission, please charge the same, or credit any overpayment, to Deposit Account No. 16-0221.

Respectfully submitted,

James A. Sheridan 4/5/04
James A. Sheridan

Registration No. 43,114

Pandiscio & Pandiscio

470 Totten Pond Road

Waltham, MA 02451-1914

Tel. No. (781) 290-0060

KK/VIA14.AMD

VIA-14

BEST AVAILABLE COPY